REMARKS

In the Office Action, claims 1, 5-13, 15-20 and 24-35 are rejected under 35 U.S.C. § 103; and claims 1, 20 and 35 are rejected under 35 U.S.C. § 112, first paragraph. Applicants believe that the rejections are improper for at least the reasons set forth below.

At the outset, claims 1, 20 and 35 have been amended. This amendment was made for clarification purposes as fully supported in the specification and thus not intended to narrow and/or disclaim any claimed subject matter in view of same.

In the Office Action, claims 1, 5-13, 15-20 and 24-35 are rejected as allegedly obvious in view of U.S. Patent No. 5,547,927 ("Cope"). Applicants believe that Cope on its own is distinguishable from the claimed invention.

Of the pending claims at issue, claims 1, 9, 19, 20, 26 and 33 are the sole independent claims. Independent claim 1 recites an infant formula that is lactose free. The infant formula includes soy hydrolysate isolate wherein the soy hydrolysate isolate has a degree of hydrolysis of approximately 4 to about 10% and wherein the infant formula further includes a stabilizer system that includes rice starch or high amylose corn starch.

Independent claim 9 recites infant formula that includes a protein source that provides approximately 0.5 to about 10% based on the weight of the formula and includes soy hydrolysate isolate; a carbohydrate source; a fat source; a stabilizer system including high amylose corn starch; and vitamins and minerals.

Independent claim 19 recites a nutritional formulation. The formulation includes a protein source that provides approximately 0.5 to about 10% based on weight of the formula and includes soy hydrolysate isolate that has a degree of hydrolysis of approximately 4 to about 10%; a carbohydrate source; a fat source; a stabilizer system that includes high amylose corn starch; and vitamins and minerals.

Independent claim 20 recites a method of providing an infant formula that is lactose free and more easily digested by infants than at least some lactose free infant formulas. The method includes using a protein source soy hydrolysate isolate wherein the soy hydrolysate isolate has a degree of hydrolysis of approximately 4 to about 10% and wherein the infant formula further includes a stabilizer system including rice starch or high amylose corn starch. Independent claim 26 recites an infant formula in liquid form. The formula includes a protein source that provides

approximately 0.5 to about 10% based upon weight of the formula and includes soy hydrolysate isolate; a carbohydrate source; a fat source; a stabilizer system that includes high amylose corn starch and carrageenan in vitamins and minerals. Independent claim 33 recites an infant formula that is lactose free. The formula includes soy hydrolysate isolate wherein the soy hydrolysate isolate has a degree of hydrolysis of approximately 4 to about 10% and wherein the infant formula includes, a percent by weight of total protein, up to 50% of intact soy protein isolate.

Applicants have discovered that by providing hydrolyzed soy a soy-based formula can be provided that is more easily digested and better tolerated and may have at least reduced allergenicity potential. Thus, the formula can be used with infants, or other individuals that may have difficulties digesting proteins. For example, the formula can be used with infants that may be fussy due to an intolerance to regular soy protein formulas. See, Specification, paragraphs 24 and 25.

In contrast, Applicants believe that the Cope reference fails to disclose or suggest the claimed invention for at least a number of reasons. At the outset, the Cope reference does not even relate to an infant formula as required by the claimed invention. Indeed, the primary focus of Cope relates to an enteral nutritional product that has been formulated for persons who are currently undergoing radiation therapy and/or chemotherapy. Clearly, one skilled in the art would consider that many differences exist between this type of enteral nutritional product as disclosed in Cope and an infant formula. For example, infant formulas are generally known to have less energy provided per volume than enteral products for adult patients. Indeed, Cope provides a high caloric density of 1.3 kcal/L (Cope, column 5, lines 9-10) where an infant formula typically has a caloric density of about 0.7-0.8 kcal/ml. Moreover, infant formulas have a completely different distribution of macro-nutrients than formulas for adult patients due to different nutritional requirements. For example, infant formulas typically have about 7-9% of the energy provided by protein. In contrast, the product disclosed in Table 6 of Cope has an amount of energy provided by protein that is estimated at 21%. Therefore, Applicants believe that one skilled in the art would not be inclined to modify the enteral nutritional product in Cope to cover infant formulas, let alone infant formulas as required by the claimed invention.

Further, Applicants believe that Cope is distinguishable from the claimed invention for additional reasons. For example, Applicants believe that Cope is deficient with respect to the

degree of hydrolysis feature as claimed. Indeed, Cope provides that it is important the degree of hydrolysis of the soy protein hydrolysate be in the range of about 14 to 17 and, most preferably, about 16. See, Cope, column 6, lines 3-6. In contrast, the claimed infant formula requires, in part, a degree of hydrolysis of approximately 4 to about 10% as defined in claims 1, 19, 20 and 33 and as further defined in claims 12 and 29. Thus, Applicants believe that Cope fails to disclose or suggest this feature to the extent that it effectively teaches away from same. Moreover, Cope fails to disclose or suggest a nutritional product, let alone an infant formula, that is lactose free as defined in claims 1, 20 and 33.

What the Patent Office has done is to rely on hindsight reasoning in support of the modification of Cope. Of course, this is clearly improper. Again, Cope is deficient with respect to at least a number of features as claimed even to the extent that Cope effectively teaches away from, at a minimum, the degree of hydrolysis as discussed above. Moreover, the Patent Office provides mere conclusions without support or motivation in Cope to remedy the deficiencies in Cope as the Patent Office has alleged. Therefore, Applicants believe that one skilled in the art would not be inclined to modify Cope to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that Cope fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully request that Cope fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

In the Office Action, claims 1, 20 and 35 are rejected under 35 U.S.C. § 112, first paragraph. The Patent Office alleges that the subject matter as defined therein is not enabled. Applicants believe that this rejection is improper and should be withdrawn.

Claims 1, 20 and 35 recite, in part, an infant formula that includes a stabilizer system including rice starch or high amylose corn starch. Support for this subject matter can be found in the specification. For example, the specification provides that neutral rice starch can be utilized to stabilize the formula emulsion where neutral rice starch provides stability as well as better hydration conditions and allows the product to be heat sterilized without degradation. The stabilizer system can include a variety of different materials, such as high amylose, corn starch, kappa or iota carrageenan and the like as further illustrated at paragraph 32. In addition,

Applicants have provided a number of different examples that further illustrate the stabilizer systems of the soy hydrolysate-based infant formula as claimed. See, Specification, paragraphs 33 and 34. Contrary to the Patent Office's position, the stabilizer systems as claimed have been sufficiently described in the specification such that one skilled in the art would be readily able to practice the claimed invention. Indeed, Applicants do not believe that one skilled in the art would necessarily consider the subject matter as claimed to be so unpredictable in nature such that the claimed invention could not be practiced without undue experimentation other than those specific examples disclosed in the specification. For at least these reasons, Applicants believe that claims 1, 20 and 35 are clearly enabled and thus satisfy the enablement requirements pursuant to 35 U.S.C. § 112, first paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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